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Innocoll
Pharmaceuticals

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FEB 1 6 2010

510(k) Summary

1. **Date Prepared:** September 1st , 2009

2. **Submitter** Innocoll Pharmaceuticals
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Ireland.
Tel: +353 (0) 9064 86834
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Submission Correspondent: Aaron Wyse
Director of Regulatory Affairs

3. **Proprietary Name:** Collagen Sponge

4. **Common Name:** Topical Wound Dressing

5. **Device Classification:** Product Code: KGN
Classification Name: Dressing Wound Collagen
Regulatory Class: Unclassified

6. **Statement of Substantial Equivalence:**

Collagen Sponge is substantially equivalent in materials of construction and intended use to CollaGUARD (K061746) and to Collieva (K081782) manufactured by Syntacoll GmbH.

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7. Intended Use

Collagen sponge may be used for the management of wounds such as:

- Pressure ulcers
- Venous stasis ulcers
- Diabetic ulcers
- First and second degree burns
- Partial and full thickness wounds
- Superficial injuries

8. Description

Collagen Sponge is a collagen matrix sponge intended for topical use. The product is supplied sterile for single use only.

9. Biocompatibility

There are no new biocompatibility issues arising with the use of Collagen Sponge as the materials of construction and finished product material match that of CollaGUARD (K061746).

10. Conclusion

Collagen Sponge is substantially equivalent to the predicate devices delineated in this submission and meets the requirements for premarket notification as defined in CFR21, Part 807.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

FEB 1 6 2010

Innocoll Pharmaceuticals
% Mr. Aaron Wyse
Director of Regulatory Affairs
Midlands Innovation & Research Centre
Dublin Road, Athlone, Co. Westmeath
Ireland

Re: K092805
Trade/Device Name: Collagen Sponge
Regulatory Class: Unclassified
Product Code: KGN
Dated: January 27, 2010
Received: February 2, 2010

Dear Mr. Wyse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092805

Statement of Indications for Use

510(k) Number (if known): _____

Device Name: Collagen Sponge

Indications For Use:

Indications:
Collagen Sponge may be used for the management of wounds such as:

- Pressure ulcers
- Venous stasis ulcers
- Diabetic ulcers
- First and second degree burns
- Partial and full thickness wounds
- Superficial injuries

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092805